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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,183	07/08/2003	Erin Jessica Lindsay	033528-001	7109
BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404			EXAMINER	
			LANG, AMY T	
Alexandria, VA 22313-1404		ART UNIT	PAPER NUMBER	
			3731	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MO	NTHS	03/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)			
	10/614,183	LINDSAY, ERIN JESSICA			
Office Action Summary	Examiner	Art Unit			
	Amy T. Lang	3731			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	l. lely filed the mailing date of this communication. 0 (35 U.S.C. § 133).			
Status		· ,			
1) Responsive to communication(s) filed on <u>08 Ja</u>					
· <u> </u>	,—				
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) Claim(s) 1-14 is/are pending in the application.					
4a) Of the above claim(s) <u>2</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) 1 and 3-14 is/are rejected.					
7) Claim(s) is/are objected to.	election requirement				
8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
9) The specification is objected to by the Examine					
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No.					
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
· · · · · · · · · · · · · · · · · · ·					
Attachment(s)					
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)					
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) 	Paper No(s)/Mail Da 5) Notice of Informal Pa				
Paper No(s)/Mail Date <u>10/15/2003</u> . 6) Other:					

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

The new grounds of rejection set forth below are necessitated by applicant's amendment filed on 1/8/2007. In particular, claims 1, 4, and 12-14. This combination of limitations was not present in the original claims. Thus, the following action is properly made final.

Response to Arguments

Applicant's arguments filed 1/8/2007 have been fully considered but they are not persuasive. Specifically, applicant argues (A) that the distal device of Haber does not overlap the instant claims.

With respect to argument (A), the device of Haber is only used to show that a handle for an endoscopic instrument as instantly claimed is known in the art.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 2. Claims 1 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 12, and 13 recite wherein the manipulator fork is extendable <u>through</u> said cone portion. However, it is the examiner's position that the instant specification only supports wherein the manipulator fork is extendable <u>from</u> the cone portion.

3. Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 4 both recite a recess in the distal exterior surface of the cone for receiving a surgical device. However, it is the examiner's position that the instant specification only supports a recess for receiving a surgical device, and not the instantly claimed recess in the exterior surface.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3, 12, and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6, and 11 of U.S. Patent No. 6,660,016 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because US '016 discloses an endoscopic apparatus comprising an endoscopic barrel including at least two lumens, one of which is dimensioned for receiving an endoscope, a handle, a fork consisting of two fingers for cauterizing tissue, and a cone placed over the distal end of the device. Although US '016 does not specifically disclose the fork as extending from the cone portion, since the cone is disposed over the fork it would have been obvious to one of ordinary skill at the time of the invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. Claims 1, 3-6, and 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Bayer (US 2004/0204725 A1).

With regard to claims 1 and 12, Bayer discloses a surgical device comprising a shaft, handle, and conical distal tip (Figure 1A). The shaft comprises a plurality of lumens, one specifically for receiving an endoscope ([0018], [0023]). Another lumen receives a ligating/cutting instrument (132) comprising jaws (134a and 134b), which clearly overlaps a dissecting instrument ([0072], [0073], Figure 3). The jaw members are initially disposed within the distal cone tip (100) when the device is in a retracted position so that the contour profile of the cone is maintained (Figure 1A). When the surgical device is ready to ligate tissue, the cone is advanced away from the jaw members (Figure 3). As shown in Figure 8, the jaws members are extended through the cone portion while dissecting the blood vessel (200). Therefore, the cone provides a recess for receiving the fork.

With regard to **claims 3, 4, 11, 13, and 14**, Bayer specifically discloses the shaft comprising an additional lumen receiving a surgical instrument ([0094]).

With regard to **claim 5**, Bayer discloses toggle members (31a and 31b) that controls translational and rotational of the shaft (12) and tip (100) ([0077]). Therefore, since the ligating/cutting fork (132) is disposed in the conical tip (100), the fork is intrinsically controlled by the toggle members.

With regard to **claim 6**, the fork instrument (132) of Bayer comprises jaw members (134a and 134b) ([0078]). Therefore, it is the examiner's position that

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member 134a overlaps the instantly claimed fork arm and member 134b overlaps the instantly claimed distal fork.

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 10. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer (US 2004/0204725 A1) in view of Haber (US 5,282,806).

Bayer discloses the rotatable control assembly disposed on a track on the handle, used for actuating rotational and translational movement of the tip and shaft of the instrument (paragraph 0077). Haber discloses an endoscopic instrument with a manipulator fork comprising a distal fork and a fork arm. The handles on Haber's instrument actuate rotational movement, or swiveling, of the fork, as well as movement of the distal jaws of the manipulator (col. 4, lines 37-65). The swivel control tube (8)

causes the manipulator to rotate when the handles are engaged. Bayer discloses the use of various endoscopic instruments with his device, such as the instrument of Haber. Therefore, it would have been obvious to one of ordinary skill in the art to use the instrument of Haber in the device of Bayer.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Lang whose telephone number is (571) 272-9057.

The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/14/2007 Amy T. Lang

> ANHTUANT. NGUYEN SUPERVISORY PATENT EXAMINER